

Message Text

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PAGE 01 STATE 180665

11
ORIGIN HEW-08

INFO OCT-01 EUR-06 ISO-00 SCI-06 SCSE-00 RSC-01 /022 R

DRAFTED BY DHEW/FDA:LRSHELTON

APPROVED BY SCI/SA:MSBEAUBIEN

EUR/CE:BFLATIN

DHEW/OIH:MACODDING

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R 162156Z AUG 74
FM SECSTATE WASHDC
TO AMEMBASSY VIENNA

UNCLAS STATE 180665

E.O. 11652: N/A

TAGS: CASC, AU(MAHLER, MARY L.)

SUBJECT: MEDICATION FOR MARY L. MAHLER

REF: VIENNA 6913

STATE 171132

GEROVITAL AND ASLAVITAL ARE REGARDED AS NEW DRUGS AS THAT TERM IS DEFINED BY THE FEDERAL FOOD, DRUG AND COSMETIC ACT. THE ACT PROHIBITS INTERSTATE SHIPMENT OF A NEW DRUG, INCLUDING THE IMPORTATION THEREOF, WITHOUT APPROVAL OF A NEW DRUG APPLICATION EFFECTIVE WITH RESPECT TO THAT DRUG. THE ONLY EXCEPTION TO THIS RULE IS WHEN THE ARTICLE IS EXEMPT FROM THE BAN ON INTERSTATE DISTRIBUTION OF UNAPPROVED NEW DRUGS BY VIRTUE OF THE FACT THAT IT IS INTENDED SOLELY FOR INVESTIGATIONAL USE AND IS COVERED BY A NOTICE OF CLAIMED INVESTIGATIONAL EXEMPTION ON FILE WITH FDA. THERE IS NOT ON FILE WITH THE FDA AN APPROVED NEW DRUG APPLICATION PROVIDING FOR THE COMMERCIAL DISTRIBUTION OR IMPORTATION OF GEROVITAL OR ASLAVITAL. ONE FIRM, ROM-AMER PHARMACEUTICALS OF BEVERLEY HILLS, CALIFORNIA HOLDVNG NOTICE OF CLAIMED EXEMPTION FOR GEROVITAL H-3 PURSUANT TO THIS EXEMPTION THAT MAY HANDLE INTERSTATE SHIPMENT OF GEROVITAL H-3 INTENDED SOLELY FOR DISTRIBUTION TO QUALIFIED EXPERTS WHO ARE CONDUCTING CLINICAL INVESTIGATIONS TO DEEM ITS SAFETY AND UNCLASSIFIED

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EFFECTIVENESS. WITH THIS SINGLE EXEMPTION FDA CANNOT

APPROVE RELEASE FOR IMPORTATION OF GEROVITAL H-3 OR
ASLAVITAL. KISSINGER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: n/a
Control Number: n/a
Copy: SINGLE
Draft Date: 16 AUG 1974
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1974STATE180665
Document Source: CORE
Document Unique ID: 00
Drafter: LRSHELTON
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D740226-1189
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1974/newtext/t19740840/aaaabhv.u.tel
Line Count: 63
Locator: TEXT ON-LINE, ON MICROFILM
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 2
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: VIENNA 6913
Review Action: RELEASED, APPROVED
Review Authority: martinjw
Review Comment: n/a
Review Content Flags:
Review Date: 09 OCT 2002
Review Event:
Review Exemptions: n/a
Review History: RELEASED <09 OCT 2002 by ReddocGW>; APPROVED <23 JAN 2003 by martinjw>
Review Markings:

Declassified/Released
US Department of State
EO Systematic Review
30 JUN 2005

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: MEDICATION FOR MARY L. MAHLER
TAGS: CASC, AU, (MAHLER, MARY L)
To: VIENNA
Type: TE
Markings: Declassified/Released US Department of State EO Systematic Review 30 JUN 2005